

Notice of Allowability

Application No.

09/963,341

Applicant(s)

MATTES ET AL.

Examiner

Susan Hanley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/24/05.
2. ☒ The allowed claim(s) is/are 59,61,62,64-66 and 68-76.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/963,341.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>6/10/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Claim Renumbering

The amended claims filed 3/24/05 contained two new claims that were both numbered as "74". According to Rule § 1.126, the second claim having the designation of "74" is renumbered as "75" to maintain consecutive numbering of the claims.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick Eagleman on 6/10/05.

The application has been amended as follows:

Claim 59 has been replaced by the following:

--59. A method of preparing a purified biologically active alpha 1-antitrypsin (α 1-AT) preparation containing an α 1- AT isomer having a pl of between 4.3 and 4.4 comprising: providing a starting material containing active and inactive α 1-AT, wherein the starting material is a plasma fraction obtained from pooled human plasma; providing a hydroxyapatite substrate; passing said starting material containing α 1-AT over said hydroxyapatite substrate; eluting a biologically active α 1-AT biologically active α 1-AT preparation having a pl of between 4.3 and 4.4; and passing said biologically active α 1-AT preparation over an anion exchange material in the presence of a detergent. --

Claim 60 has been cancelled.

Claims 61 and 62 have been replaced by the following:

--61. The method according to claim 59, wherein said eluting step is on said hydroxyapatite is conducted with a buffer having a pH of between 5.5 and 8.0.

Art Unit: 1651

62. The method according to claim 61, wherein said eluting step on hydroxyapatite is conducted with a buffer having a pH of between 6.5 and 6.8. --

Claim 67 has been cancelled.

Claims 69-71 have been replaced by the following:

-- 69. The method according to claim 59, wherein said eluting step on said hydroxyapatite is conducted with a buffer which comprises a salt having an ionic strength corresponding to 60 mM of phosphate.

70. The method according to claim 59, wherein said eluting step on said hydroxyapatite is conducted with a buffer which comprises a salt having an ionic strength corresponding to 40 mM of phosphate.

71. The method according to claim 59, wherein said eluting step on said hydroxyapatite is conducted with a buffer which comprises a salt having an ionic strength corresponding to 50 to 130 mM of phosphate. --

Claims 74 and 75 have been replaced by the following:

-- 74. A method for purifying biologically active α 1-AT including α 1-AT isomers having pIs of between 4.3 and 4.4 from an alpha 1-AT-containing fraction which is obtainable from a human plasma pool comprising: Adjusting the pH of said α 1-AT-containing fraction to about 6.5, absorbing said acidified α 1-AT-containing fraction onto a chromatographic anion exchanger in the presence of a detergent, and eluting said biologically active α 1-AT from said chromatographic anion exchanger including α 1-AT isomers having pIs of between 4.3 and 4.4.

75. A method according to claim 74 in which said elution is carried out at a pH ranging between 5.5 and 8.0. --

New claim 76 has been added:

-- 76. A method according to claim 74 in which said elution is carried out at a pH ranging between 6.5 and 6.8. --

Claims 59, 61, 62, 64--66 and 68-76 have been allowed.

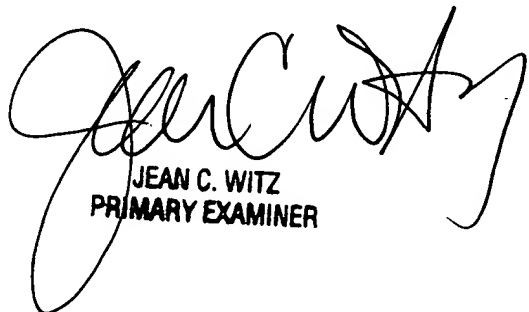
Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
AU 1651



JEAN C. WITZ
PRIMARY EXAMINER